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10/544,281	08/03/2005	Laura Quaranta	70220 9446	
	7590 01/25/200 ROP PROTECTION ,	EXAMINER		
PATENT AND	TRADEMARK DEPA	QAZI, SABIHA NAIM		
410 SWING RO GREENSBORO			ART UNIT	PAPER NUMBER
	•	1616		
SHORTENED STATUTORY	PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Applie	cation No.	Applicant(s)	
Office Action Summary		10/54	4,281	QUARATA	
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Period fo	The MAILING DATE of this commun	nication appears or	the cover sheet	with the correspondence a	ddress
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE Manisons of time may be available under the provisions SIX (6) MONTHS from the mailing date of this coming period for reply is specified above, the maximum is the reply within the set or extended period for reply reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF s of 37 CFR 1.136(a). In munication. latutory period will apply a y will, by statute, cause the	THIS COMMUN to event, however, may a and will expire SIX (6) MC application to become a	ICATION. a reply be timely filed DNTHS from the mailing date of this ABANDONED (35 U.S.C. § 133).	,
Status					
2a) <u></u>	Responsive to communication(s) file This action is FINAL . Since this application is in condition closed in accordance with the pract	2b)⊠ This action for allowance exc	is non-final. ept for formal ma	·	ne merits is
Dispositi	ion of Claims				
5)☐ 6)⊠ 7)☐ 8)☐ Applicati 9)☐ 10)☐	Claim(s) 1-4,7 and 8 is/are pending 4a) Of the above claim(s) is/a Claim(s) is/are allowed. Claim(s) 1-4 and 7-8 is/are rejected Claim(s) is/are objected to. Claim(s) are subject to restrict on Papers The specification is objected to by the the drawing(s) filed on is/are Applicant may not request that any objected to an including	e Examiner. a) accepted of the correction is received.	consideration. on requirement. r b) objected to (s) be held in abeya quired if the drawing	ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 C	
	The oath or declaration is objected to	o by the Examiner.	. Note the attache	ed Office Action or form P	TO-152.
12)[a)[Acknowledgment is made of a claim All b) Some * c) None of: 1. Certified copies of the priority 2. Certified copies of the priority 3. Copies of the certified copies application from the Internationsee the attached detailed Office actions	documents have to documents have to of the priority document Bureau (PCT)	peen received. peen received in a aments have been Rule 17.2(a)).	Application No n received in this Nationa	l Stage
2) Notice 3) Inform	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (F nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	PTO-948)	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application 	•

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Non-Final Office Action

Claims 1-4, 7 and are pending. No claim is allowed at this time.

Summary of this Office Action dated 01/20/2007

- 1. Information Disclosure Statement
- 2. Copending Applications
- 3. Specification
- 4. 35 USC § 103(a) Rejection---1st Rejection
- 5. 35 USC § 103(a) Rejection---2nd Rejection
- 6. Response to Remarks
- 7. Communication

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 USC § 112 --- First Paragraph Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-4, 7 and 8 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no possession of the invention of the subject matter as claimed at the time of filing the application. Applicant is kindly requested to explain the issue.

See MPEP 2163.06, for Applicant's convenience relevant part is cited as follows.

GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE "WRITTEN DESCRIPTION" REQUIREMENT FOR APPLICATIONS

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). >See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description").< The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the

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information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. Enzo Biochem, Inc. v. Gen-Probe, Inc., **>323 F.3d 956, 969-70,< 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. See, e.g., Martin v. Mayer, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987). In addition, early opinions suggest the Patent and

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Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55. 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a factbased inquiry that will 'necessarily vary depending on the nature of the invention claimed." Enzo Biochem, **>323 F.3d at 963<, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological

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materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq. See Enzo Biochem, **>323 F.3d at 965<, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material"); see also Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." ld. at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement." Id. at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., In re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Enzo Biochem*, **>323 F.3d at 968<, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed

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(see, e.g., In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (see, e.g., New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); Tronzo v. Biomet, Inc., 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); In re Ziegler, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

35 U.S.C. 112 Specification. - Patent Laws

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim Rejections - 35 USC § 103—1st Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over LINN et al.¹. The reference teaches avermectin derivatives useful for controlling pests, which embraces Applicant's claimed invention. The reference teaches avermectin compounds wherein 4" or 4' hydroxyl group is oxidized to an oxo group and replaced with semicarbazone, carbonyl- or sulfonylhydrazide or hydrazine. The compounds have utility as anti-parasitic agents. These compounds are also useful as insecticides against agricultural pests. See the entire document especially abstract, compounds of formula I on page 2, compound in lines 35-55 on page 3, m and n are 0 or 1.

Instant claims differ from the reference in that they are of different generic scope. It had been held by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. <u>In re Lemin</u>, 141 USPQ 814 (1964); <u>National Distillers and Chem. Corp. V. Brenner</u>, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds for the same use such as pesticides. The instant claimed compounds would have been suggested to one skilled in the art.

The substituents as presently claimed are generically taught by the prior art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have

¹ EPA 0343,708

been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In absence of any criticality and/or unexpected results presently claimed invention is considered obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

Examiner notes, proviso in claim 1.

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103—2nd Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over OMURA et al.².

The reference teaches avermectin derivatives having high antiparasitic activity, which embraces Applicant's claimed invention. See the entire document especially formula (1) and lines 25-55 in col. 1; preparation, Tables 1-8 in column 37-45; examples and claims.

Instant claims differ from the reference in that they are of different generic scope. (Specific compound are disclosed in present application for example see Tables 9 and 10 on pages 76 and 77.

It had been held by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. <u>In re Lemin</u>, 141 USPQ 814 (1964); <u>National Distillers and Chem. Corp. V. Brenner</u>, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds for the same use such as pesticides. The instant claimed compounds would have been suggested to one skilled in the art at the time of invention was made.

² US Patent 6,605,595 B1

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Instant claims are broader than the prior art.

10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804,

In absence of any criticality and/or unexpected results presently claimed invention is considered obvious.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

Rejection over MROZIK is withdrawn because arguments are found persuasive.

• Applicant's arguments on OMURA et al. were fully considered but are not found persuasive therefore the rejection is maintained.

Communication

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-

272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

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PRIMARY EXAMINER